

REMARKS

The applicant formally withdraws the appeal pending with respect to this application and files this Request For Continued Prosecution to respond to the concerns raised in the examiner's Answer and present amended claims for allowance.

Appeal Formally Withdrawn. The applicant formally withdraws the appeal pending with respect to application no. 09/48,299. The applicant does not waive any right to a further appeal in this matter, if the claimed subject matter as amended is again finally rejected.

Request For Continued Prosecution. The applicant makes this submission to address the examiner's concerns raised in the Answer mailed December 18, 2002 and respectfully requests examination of the claims as amended.

Formal Cancellation Of Claims. The applicant without prejudice formally cancels claims 1-37. The applicant does not waive any right to have these claims examined without any reduction in breadth in a subsequent continuing application, if desired.

Amendment. The applicant has amended and reordered the sequence of the original claims 1-26 and 35. For clarity purposes the applicant has canceled original claims 1-26 and 35 and set out the amended and reordered claim set as claims 38-65. The applicant respectfully requests entry and examination of claims 38-65 as set out above and provides the following remarks that fully address each concern raised by the Answer mailed on December 18, 2002. The applicant does not believe that the amendments necessitate any further search on the part of the examiner.

As to the concerns under section 103, it should be noted that the claims of the application have been amended to include additional limitations supported by the specification. The applicant has selected these limitations solely to expedite the examination of this application. The applicant believes that these limitations are

allowable based on the examiner's prior completed search and prior communications including the interview of December 18, 2001.

In spite of the amendment, the applicant continues to respectfully disagree on the issue as to whether the previously cited references actually make the claims as originally recited obvious. However, so that the intended legal effect may be properly understood in light of recent case law, all third persons should understand that the proposed amendment is made only as a practicality to permit proceeding efficiently on certain claims as part of a request for continued examination in this immediate application.

The amendments should not be interpreted as an action that in any way surrenders a particular equivalency, surrenders any patent coverage, surrenders any right to patent coverage, restricts the scope of protection intended, or otherwise limits any rights which the applicant may now or hereafter assert. In particular, it should be noted that all rights to pursue the claims as originally recited and to pursue cancelled claims are expressly reserved.

Section 103 Concerns. The applicant provides the following remarks to address the 103 concerns of the examiner raised in the Examiner's Answer mailed December 18, 2002 which are in addition to those provided in Appellant's Brief submitted October 7, 2002. Appellant's Brief attached as Exhibit A; Examiner's Answer attached as Exhibit B.

The examiner first raises the concern that the Salisbury reference teaches "viable sperm". The examiner has improperly broadened the applicant's definition of "selected sperm sample" to include the products taught by Salisbury. "Selected sperm" as defined in the description does not include all manner of "viable sperm" and only includes "sperm that has been subdivided based on presence or absence of a specific characteristic. . . a selected sperm sample is therefore enriched, relative to the source sample, in sperm having the specific characteristic". Specification at page 4, ll. 9-13. For example certain embodiments of the invention include, "sperm selected from a source sample for a

characteristic. . . include frozen sex-selected human, bovine, equine, ovine, elk, or bison. Sex-selection is preferably carried out using flow cytometry. . .” Specification at page 17, ll. 19-25. Salisbury does not teach any aspect of “selected sperm” as defined by the applicant and certainly does not teach any aspect of freezing “selected sperm” as defined by the applicant.

The examiner then raises a concern that “any sperm sample which is obtained is selected” and “Salisbury is clear that the semen is obtained”. Answer at pages 6 and 7. Again, the examiner fails to use explicit definition provided by the applicant which controls the interpretation of “selected” as it is used in the claim. MPEP, § 2106. As such “selected” is not so broad as to encompass simply obtaining the sperm sample.

The examiner further raises a concern that Spaulding “contemplates” viable sperm. Answer at page 6. First, the applicants argument is confined to the limitations set out by original claim 1, element f. which limits sperm to fertile frozen selected sperm cells. The examiner’s citation at col.5, ll. 4-8 does not include any freezing limitation at all. The Spaulding reference simply does not teach “fertile frozen selected sperm”.

As such, the combination of references do not teach the limitation of fertile frozen selected sperm cells nor does the combination suggest that “fertile frozen selected sperm” can be obtained through the combined teachings.

Moreover, the combination of references does not provide any expectation of successfully making the invention of “fertile frozen selected sperm cells”. The Salisbury reference makes this unequivocally clear.

First, that there is a “test” to determine efficacy of any freezing procedure. The test is set out in Salisbury.

“Spermatozoa must be alive to be fertile. . .motility does not guarantee that such cells are fertile. . .the integrity of the genetic material in the sperm chromatin must also be preserved. . .extending media and storage conditions should preserve both functions

but there is no test of semen quality prior to use that can predict how well the genetic material is maintained."

Salisbury, Chapter 16, page 442 (emphasis added).

The importance of this test is emphasized throughout the reference by repetition:

"The end fertility level is the ultimate test of superiority of any semen handling method." Salisbury, Chapter 17, page 532.

"Although the ultimate test of a procedure is fertility (141). . ." Salisbury, Chapter 17, page 534.

The reason fertility testing is the ultimate test is because other measures of sperm cell viability do not prove fertility in practice. For example, "In general, the more rapid thawing rates resulted in better motility and retention of the acrosomal cap (249). These results (202) disagree with the fertility results obtained by Bean (149)." Salisbury, Chapter 17, page 534.

For convenience the applicant has attached the pages from Salisbury containing the above cited references as Exhibit C with the specific language highlighted.

It is clear from the offices own cited references that unless artificial insemination with frozen and subsequently thawed semen results in pregnancies the combination of references do not provide the requisite suggestion, or expectation of success required to make a case of obviousness under the rules. §2141, MPEP.



While the applicant respectfully disagrees with the examiner that the combination of Salisbury and Spaulding makes the original limitations of claim 1 obvious, the applicant for expediency only has amended original claim one (now set out as claim 38) to further include the further limitations of "sorting said sperm cells based sex-type" and "freezing said sex-selected sperm cells in said extender to provide fertile sex-selected sperm cells upon thawing". "Sorting" is clearly defined in the specification as "a selection method carried out using a fluorescence-activated cell sorter" Specification

page 4, ll. 14-15. "Sex-type" is defined as "the type of sex chromosome present in the sperm (i.e., the X or Y chromosome)." Specification at page 3, ll. 29-30.

The combination of Salisbury and Spaulding do not teach the limitation of "sorting" and do not teach the limitation of "fertile sex-selected sperm cells upon thawing".

The applicant believes that the claims as amended are now in condition for allowance and respectfully request that the examiner conduct a telephone interview to address any outstanding issues.

Version With Markings To Show Changes Made. Pursuant to 37 C.F.R. §1.121, the applicant submits a marked up version of the claims to show changes made beginning on the next full page:

VERSION WITH MARKINGS TO SHOW CHANGES MADE

The applicant has canceled claims 1-37 without prejudice.

The applicant has added claims 38-65 as set out above.

CONCLUSION

The applicant withdraws the appeal pending in this application. The applicant makes this submission along with Exhibits A-C as a request for continued prosecution. Claims 1-26 and 35 have been canceled and replaced the claim set with claims 38-60. The applicant respectfully requests continued prosecution of claims 38-60.

Dated this 18th day of February 2003.

Respectfully Submitted,
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IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

n Re the Application of: John L. Schenk

Serial Number: 09/478,299

Filed: January 5, 2000

Parent Title: Method of Cryopreserving Selected Sperm Cells

Group Art Unit: 1654

Examiner: M. Meller

Assignee: XY, Inc.

EXHIBIT A

Attorney Docket: XY Frozen RCE
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EXHIBIT B

Attorney Docket: XY Frozen RCE
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EXHIBIT C